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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,673

09/17/2007

Robert Danziger

05-159-A

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20306

7590

11/10/2009

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EXAMINER

BAEK, BONG-SOOK

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

11/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,673	Applicant(s) DANZIGER, ROBERT	
	Examiner BONG-SOOK BAEK	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/8/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/8/2006 and 7/28/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

Claims 1-17 are currently pending.

Election/Restrictions

Applicants' election of group II drawn to a method and election of rolipram as a single disclosed species of PDE inhibitor, in the reply filed on 8/13/2009 are acknowledged. The election was made without traverse.

Claims 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Claims 1-13 are under examination in the instant office action.

Priority

The instant application is a 371 of PCT/US05/005626 filed on 02/22/2005, which claims for domestic priority to US provisional application 60/546,227 filed 02/20/2004 and 60/549,289 filed on 3/2/2004 under 35 U.S.C. 119(e).

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be 02/20/2004.

Information Disclosure Statement

Signed and initialed copies of the information disclosure statement filed on 8/8/2006 and 7/28/2009 are enclosed in this action.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by WO

2004/105751 (filing date: 5/28/2003, hereafter Barone *et al.*).

Barone *et al.* teaches a method of treating hypertension in a mammal, comprising administering an effective amount of PDE4 inhibitor such as rolipram (claims 1, 5, and 7-8). It further teaches the use of PDE4 inhibitor includes veterinary use as well as human use (p10, lines 9-13 and p4, lines 22-24). The subject undergoing the method of the reference implicitly encompasses patients suffering from all types of hypertension including salt-sensitive hypertension. Furthermore, the patient population of the instant invention substantially overlaps with that of the reference as evidenced by Weinberger *et al.* (Hypertension, 8 (Suppl II): II-127-II-134, 1986), which teaches that more than 51% of patients with hypertension are classified as salt-sensitive, 16% as salt resistant, and the remaining as having an intermediate response (abstract and pII-129, table 1). Thus the teaching of treating hypertension with rolipram reads on the instant claims.

The PDE inhibitor used in the method of the reference is the same compound as the instant application (rolipram), thus it meets limitations recited in claims 2-10. Furthermore,

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Applicant states that claims 1-13 reads on the elected species, rolipram, thus rolipram as PDE4 inhibitor must have the properties recited in claims 2-10.

As such, the instant claims are anticipated by Barone *et al.*

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
/Bbs/

BONG-SOOK BAEK
Examiner, Art Unit 1614